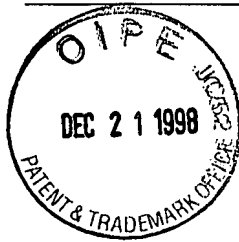




DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



DEC 17 1998

Food and Drug Administration
Rockville MD 20857

Re: Therma Choice™ Uterine Balloon Therapy System
Docket No. 98E-0850

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,949,718 filed by Gynelab Products, Inc. under 35 U.S.C. § 156. The medical device claimed by the patent is Therma Choice™ Uterine Balloon Therapy System, which was assigned premarket approval application (PMA) No. P970021.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The PMA was approved on December 12, 1997, which makes the submission of the patent term extension application on February 6, 1998, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

(for) Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Talivaldis Cepuritis
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